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| 10/521,886 | 07/05/2005 | Robert Kopesky | 60282-USA | 8844 |

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| EXAMINER | |
|---|---|
| BLAND, LAYLA D | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/521,886 | KOPESKY ET AL. | |
| | Examiner | Art Unit | |
| | Layla Bland | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/27/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This office action is a response to applicant's amendment and remarks submitted September 27, 2007, wherein claim 1 is amended. This application is a national stage entry of International Application PCT/US03/22988 and claims priority to U.S. Provisional Application No. 60/398,903. Claims 1-31 are pending in this application and are examined on the merits herein.

The objection to claim 1 for not ending with a period is withdrawn in view of applicant's amendment submitted September 27, 2007.

The rejection of claims 1-3 and 8-31 under 35 USC 112, second paragraph, for being indefinite as to the relative term "elevated" is withdrawn in view of applicant's remarks submitted September 27, 2007.

The following rejections of record are maintained:

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-7 include the limitation "at least about," which is a relative term and renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Response to Arguments***

Applicant's arguments filed September 27, 2007 have been fully considered but they are not persuasive.

Applicant argues that "about 40°C" is mentioned in the specification separately from "about 50 to 110°C," and thus, the skilled person would draw the conclusion that "about" means ±5°C. A preferred example is not a clear definition. The Federal Circuit in *Amgen, Inc. v. Chugai* held that a word of degree can be indefinite when it fails to distinguish the invention over the prior art and does not permit one of ordinary skill to know what activity constitutes infringement. 927 F.2d 1200, 1218 [18 USPQ2d 1016 <http://iplaw.bna.com/iplw/display/link_res.adp?fedfid=5895084&fname=uspq2d_18_1016&vname=ippqcases2>] (Fed. Cir. 1991). The recitation "at least about 160,000" have been held indefinite. *Id.* at 1203.

Applicant argues that 64,946 US patents issued since 1976 employ the phrase "at least about," which applicant argues gives an indication that the phrase is definite. **Applicant arguments are not found convincing since each application for patent is examined on its own merits, and patents are property and not available as precedent.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17, 20, 22-24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna, et al. (U.S. 6,228,213 B1, May 8, 2001) in view of Schaible, et al. (WO 01/05441 A1, January 11, 2001) and Trusovs, et al. (U.S. 6,392,034 B1, May 21, 2002).

Hanna, et al. teach a process for the production of microcrystalline cellulose by reactive extrusion. The process involves feeding cellulose into an extruder with a barrel. Acid and cellulose-containing material (pure cellulose can be used) are premixed and fed through the extruder or simultaneously fed into the extruder [column 3, lines 34-39]. Preferably, the temperature of the extruder barrel is about 80°C to 200°C, and most preferably 140°C [column 3, lines 60-65]. Different heating regimes affect the resulting particle size of the product and particles smaller than 200 microns can be created [column 5, lines 57-58]. The measured level-off degree of polymerization varies with the starting material and is 220 for wood-cellulose microcrystals [column 5, lines 66 and 67 and column 6, lines 1-3]. The cellulose is pressurized by the screw of the extruder and is hydrolyzed by acid. The ratio of acid solution to cellulose is approximately 1:1 [column 4, lines 19-22]. The extrusion is

preferably a continuous process [column 4, lines 8-9] and results in reaction times which are shorter than conventional methods [column 4, lines 22-25]. After extrusion, the cellulose product is washed, bleached, and dried [column 2, lines 56-64]. The product can be bleached with hydrogen peroxide [column 4, lines 44-46]. After being bleached, the product is dried by spray drying [column 4, lines 55-60]. The microcrystalline cellulose can also be manufactured using a twin screw extruder [column 5, lines 32-33].

Hanna, et al. do not teach a process for producing microcrystalline cellulose using an active oxygen compound. Hanna, et al. are silent on the exact pressure used in the method, the pH of the reaction mixture and the residence time of the extrusion.

Schaible, et al. teach a process for the production of microcrystalline cellulose comprising hydrolyizing pulp with active oxygen [see abstract]. Specific examples of active oxygen compounds include hydrogen peroxide [page 6, line 15]. The method simultaneously hydrolyzes and bleaches the starting material to obtain a high grade microcrystalline cellulose product [page 2, lines 20-24]. The reaction can be performed under increased temperature and pressure, the optimization of which can be ascertained by one skilled in the art [page 7, fourth paragraph]. The method of Schaible, et al. results in microcrystalline cellulose having a degree of polymerization as low as 208 [Example 17].

Trusovs, et al. teach a method of producing microcrystalline cellulose comprising the addition of hydrogen peroxide. Hydrogen peroxide depolymerizes the substrate and reduces viscosity [column 2, lines 49-54].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use reactive extrusion with hydrogen peroxide to produce microcrystalline cellulose. The skilled artisan would have been motivated to do so with an expectation of success because the extruder method has a shorter reaction time than conventional methods and the use of hydrogen peroxide for hydrolysis also bleaches the material at the same time, so there is no need for a separate bleaching step. It is considered within the skill of one of ordinary skill in the art to optimize parameters such as pressure, time, concentration, and order of addition of reagents. The pH of the reaction mixture during extrusion is an intrinsic feature of the solvents and reagents used in the reaction. Because hydrogen peroxide is known to depolymerize cellulose under standard reaction conditions (Trusovs, et al.), it is considered obvious to hold the reaction mixture after shearing to further depolymerize the material.

Claims 18-21, 25-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna, et al. (U.S. 6,228,213 B1, May 8, 2001) in view of Schaible, et al. (WO 01/05441 A1, January 11, 2001) and Trusovs, et al. (U.S. 6,392,034 B1, May 21, 2002) as applied to claims 1-17, 22-24 and 28 above, and further in view of McGinley, et al. (U.S. 5,192,569, March 9, 1993).

Hanna, et al., Schaible, et al., and Trusovs, et al. teach as set forth above.

Hanna, et al., Schaible, et al., and Trusovs, et al. do not teach attriting the microcrystalline cellulose product or the addition of an additive.

McGinley, et al. teach the production of colloidal grades of microcrystalline cellulose by attriting the wetcake after filtration and washing steps, at which time additives such as sodium carboxymethylcellulose (a barrier dispersant) can be added [column 4, lines 63-69]. The attrited, colloidal microcrystalline cellulose may then be dried [column 5, lines 1-3]. Microcrystalline cellulose can be used with other cellulosic materials such as carboxymethylcellulose to form a water-dispersible colloid for use as a stabilizing agent and to enhance the texture of foods [column 1, lines 48-54].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce attrited, dried microcrystalline cellulose and to add an additive to the product. The skilled artisan would have been motivated to do so with an expectation of success in order to create a colloidal product which can be used as a food additive, as taught by McGinley, et al.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Response to Arguments***

Applicant's arguments filed September 27, 2007 have been fully considered but they are not persuasive.

Applicant argues that the skilled artisan would not substitute an active oxygen treatment for the acid hydrolysis of Hanna et al. because the two are not chemical equivalents and treatment with peroxide can cause "some oxidation" of the cellulose. Applicant asserts that the oxidation would likely result in a significant chemical change in the cellulose not contemplated by Hanna et al. and would result in materially changed properties of the cellulose. The motivation for the skilled artisan to combine the above references need not be to arrive at cellulose chemically identical to that taught by Hanna et al. The skilled artisan would have been motivated to combine the extrusion process of Hanna et al. with the reactive oxygen method of Schaible et al. for the reasons given above.

Applicant argues that neither Schaible et al. nor Trusovs et al. relate to the conventional methods referred to be Hanna et al. Hanna et al. teach that in conventional methods, MCC is formed by reacting cellulose with acid in a batch-type reaction vessel [column 1, lines 40-47]; and conventional methods do not contemplate the advantage of using pressure and high shear forces [column 2, lines 5-6]; and the high pressure applied by the extruder creates high shear forces and allows the reaction to be accomplished in a much shorter time as compared with conventional technology [column 4, lines 22-25]. The skilled artisan would interpret this teaching to mean that

acid hydrolysis at high temperature and high shear forces is faster than acid hydrolysis without high temperature and high shear forces. The skilled artisan could easily apply this logic to the reaction with reactive oxygen.

Applicant argues that, in the method of Hanna et al., a bleaching step is not always necessary. Indeed, Hanna et al. teach that if pure cellulose is the starting material, it is not necessary to go through the bleaching step because pure cellulose is already pre-bleached. However, it is clear that in many cases, a bleaching step is part of the process taught by Hanna et al.

Applicant argues that it is not clear that the effectiveness of the bleaching in the processes of Shiable et al. and Trusovs et al. is sufficient to obviate the need for a separate bleaching step and that inclusion of a peroxide in the extruder method of Hanna et al. would necessarily eliminate the need for a further bleaching step, since other factors, such as the starting material employed, should be considered. Schaible et al. teach that their method of producing microcrystalline cellulose utilizing active oxygen bleaches and hydrolyzes pulp in a one-step process [page 5, first paragraph]. This teaching provides the skilled artisan with a motivation to use active oxygen, as taught by Schaible et al., and a reasonable expectation of success.

In response to applicant's argument that Trusovs et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this

case, Trusovs et al. is concerned with the production of microcrystalline cellulose, as is the instant application. Thus, Trusovs et al. is considered to be in the field of applicant's endeavor. Moreover, Trusovs et al. is primarly used to show that hydrogen peroxide is known in the art to depolymerize and reduce the viscosity of cellulose during the production of microcrystalline cellulose.

Applicant argues, with respect to product claims 22-24 and 26, that the skilled person would expect that these products would be different from those produced by acid hydrolysis according to Hanna et al. The rejection is not based on the method of Hanna et al.; rather, it is based on the combined references as discussed above.

Applicant's arguments with respect to claims 18-21, 25-27, and 29-31 are based on applicant's previous arguments, which have been addressed above.

## *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
October 19, 2007

Shaojia Anna Jiang

10/24/07

Supervisory Patent Examiner
Art Unit 1623
October 19, 2007